Purina Mills, Inc.

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

July 16, 1999

(Docket No. 99N-1591)
Animal Drug Availability Act; Veterinary Feed Directive
Proposed Rule

Purina Mills Inc. is a major manufacturer and distributor of animal feed, including medicated feed, and therefore has a vital interest in the agencies effort to promulgate regulations for the implementation of the Animal Drug Availability Act (ADAA). Considering that a drug restricted to VFD requirements has been marketed for the past few year since the ADAA was signed into law 10/9/96, Purina and other VFD feed manufacturers and distributors have had practical experience in compliance with requirements established by ADAA.

Purina overall is very supportive of the regulations that would be established by these proposed regulations. In general, the regulations mirror what is actually being practiced today. There are however, a few points of the proposed rule that need to be addressed to strengthen the regulatory program to be established.

- sec 558. (3) (11) should be expanded to include the following sentence; "An acknowledgment letter and the "notification letter" (as required by sec 558.6 (d) (1) (I)), can be combined into a single letter that includes all information required for the "notification letter" and "acknowledgement letter"".

  This permits the VFD manufacturer or distributor to develop a single document for submission to CVM and VFD drug sources, rather than having to develop separate letters.

- The agency asked for comment relative to the use of fax, phone, and e-mail for initial transmission of the VFD followed by the actual VFD. Purina is opposed to the use of any of these types of transmission. It is very difficult to substantiate the authenticity of the VFD through these means. In addition, if the actual VFD is not received who is held responsible, the veterinarian, feeder, or the feed manufacturer. Purina believes that the VFD should be available at the feeder or distributor site to be effective.

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- The agency asked if the veterinarian should be permitted to use his own form, or be required to use the form developed by the type A drug sponsor. The proposed rule would require the type A drug sponsor to include the form as part of his new animal drug application, but does not require the veterinarian to use the form. Purina believes that the type A drug sponsor form should be required to be used by the veterinarian to assure that the appropriate information required by the VFD drugs regulation is covered in the actual VFD. In addition, the regulation should require that the VFD be fully completed, no blanks. If the veterinarian is permitted to use his own form, and then if the information provided on the form is not complete or is not in accordance with the drugs regulation, who is held accountable? The veterinarian, the distributor, or both? We believe a requirement to fully complete the drug sponsor's form would eliminate this question as the VFD would not be acceptable until it's fully completed.

- sec 558.6 (a) (3), add the word fully so that the section reads; "You must fully complete the VFD in writing and sign it"

- Sec 558.6 (a) (4), Expand the sentence to read; "You must produce the VFD in triplicate using only the form provided by the type A drug sponsor".

- sec 558. 6 (b) (4), change this section to read; "You must give a VFD to the client or distributor."

- sec 558. 6 (c) (3), should be removed in it's entirety for the reasons stated above.

Purina Mills appreciates this opportunity to comment and trusts that the agency will find our thoughts helpful. If you need any further information or clarification of our comments, please phone me 314 768-4492.

Sincerely,

R. E. Broyles, Director
Regulatory & Quality

cc American Feed Industry Association